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DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
Food and Drug Administration
SOUTHWEST REGION

Office of the Regional
Food and Drug Director
7920 Elmbrook Drive, Suite 102
Dallas, TX 75247-4982
TELEPHONE: 214-655-8100
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WARNING LETTER

98-SWR-WL-03/0

December 11, 1997

Bernice Henseley
Owner
Beauty And The Beach
1020 Plaza Ct., Suite C
St. Clair, MO 63077

Dear Ms. Henseley:

The inspection of your tanning facility, Beauty And The Beach located at 1020 Plaza Ct., Suite C, St. Clair, MO 63077, on November 6, 1997, by Investigator Dennis Butcher revealed serious violations of the Federal Food, Drug and Cosmetic Act (the Act). The investigator documented significant items of noncompliance with the Federal Performance Standard for Sunlamp Products as prescribed in Title 21, Code of Federal Regulations, Part 1040.20 (21 CFR 1040.20) in conjunction with four tanning beds in operation at your facility. The inspection indicated the noncompliances for three of the tanning beds manufactured by International Suntan Systems (SN 84424, SN CLS 85117 and SN 84104). The fourth bed's manufacturer information was missing.

The inspection revealed that the tanning beds located in rooms 1, 2, 3 and 4 were misbranded within the meaning of Section 502(f) of the Act. There was no user instruction manuals or documentation of lamp compatibility available for these tanning beds to provide adequate directions for use in such manner as necessary for the protection of users against potentially harmful exposure to ultraviolet radiation [21 CFR 1040.20(e)(1)]. A mechanism for manual termination of radiation emission by the user was not present [21 CFR 1040.20(c)(3)]. The maximum timer interval for these tanning beds exceeded the manufacturer's recommended maximum exposure time [21 CFR 1040.20(c)]. In addition, the tanning bed in room 4 had no labeling containing the danger/warning statement [21 CFR 1040.20(d)]. This tanning bed had no certification or identification labeling present [21CFR 1010.2 and 21 CFR 1010.3].

The above identification of violations is not intended to be an all-inclusive list of deficiencies regarding sunlamp products at your firm. It is your responsibility to assure that electronic sunlamp products are maintained so that they continue to comply with the provisions of the Act.

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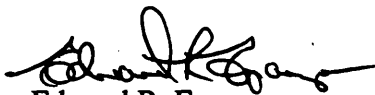
December 11, 1997

You should take prompt action to correct these violations. Failure to correct these violations may result in regulatory action, including seizure, injunction, and/or civil money penalties, without further notice.

You should notify this office in writing 15 working days of receipt of this letter, of specific steps you have taken to correct these violations. If corrections cannot be completed within 15 working days, state the reason for the delay and the time frame within which corrections will be completed.

Your reply should be directed to Deborah M. McGee, Radiation Specialist, U.S. Food and Drug Administration, 7920 Elmbrook Drive, Suite 102, Dallas, Texas 75247-4982, telephone (214) 655-8100, ext. 138.

Sincerely,

A handwritten signature in black ink, appearing to read 'Edward R. Esparza', with a stylized flourish at the end.

Edward R. Esparza
Regional Food and Drug Director
Southwest Region

DM:dm